SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SPEEDA™ Rabies Vaccine for Human Use (Vero cell), Freeze-dried, ≥ 2.5 IU/dose, Powder and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

After reconstitution, 1 dose (0.5 mL) contains:

Rabies virus* (inactivated, strain PV-2061 strain) ≥ 2.5 IU

*Produced in Vero cells

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder and solvent for suspension for injection

The powder looks like a white crisp cake. After reconstitution, it shall turn into the transparent liquid free from foreign matters

The solvent is clear, colorless liquid, odorless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Rabies Vaccine for Human Use (Vero cell), Freeze-dried for pre-exposure prophylaxis and post-exposure prophylaxis against rabies in all age groups (see Section 4.2 and 5.1)

The use of Rabies Vaccine for Human Use (Vero cell), Freeze-dried should be based on official recommendations.

4.2 Posology and method of administration

Posology

The recommended dose is 0.5 mL of reconstituted vaccine.

Pre-exposure prophylaxis

The primary pre-exposure immunisation course consists of 3 doses: one at D0, D7 and either D21 or D28.

In immunocompetent individuals, a one-week regimen with 2 doses can be used: one at D0 and D7.

For individuals at continued risk, booster doses should be given in line with official recommendations.

The need for serology testing to detect the presence of rabies virus-neutralising antibodies (≥0.5 IU/ml) should be assessed and conducted, if appropriate, in accordance with official recommendations.

Post-exposure prophylaxis

Post-exposure prophylaxis should be initiated as soon as possible after suspected rabies exposure. In all cases, proper wound care (thorough flushing and washing of all bite wounds and scratches with soap or detergent and copious amounts of water and/or virucidal agents) must be performed immediately or as soon as possible after exposure). It must be performed before administration of rabies vaccine or rabies immunoglobulin, when they are indicated.

The rabies vaccine administration must be performed strictly in accordance with the category of exposure, the patient immune status, and the animal status for rabies (according to local official recommendations, see Table 1 for WHO recommendations).

Table 1: WHO category of severity of exposure

Category of exposure	**Type of exposure to a domestic or wild animal suspected or confirmed to be rabid or animal unavailable**	**Recommended post-exposure prophylaxis**

	for **testing**	
I	Touching or feeding of animals Licks on intact skin (no exposure)	None, if reliable case history is available [a]
II	Nibbling of uncovered skin Minor scratches or abrasions without Bleeding (exposure)	Administer vaccine immediately Stop treatment if animal remains healthy throughout an observation period of 10 days [b] or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques. Treat as category III if bat exposure involved.
III	Single or multiple transdermal [c] bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to direct contact with bats. (severe exposure)	Administer rabies vaccine immediately, and rabies immunoglobulin, preferably as soon as possible after initiation of post-exposure prophylaxis. Rabies immunoglobulin can be injected up to 7 days after administration of first vaccine dose. Stop treatment if animal remains healthy throughout an observation period of 10 days or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques.

a If an apparently healthy dog or cat in or from a low-risk area is placed under observation, treatment may be delayed.

b This observation period applies only to dogs and cats. Except for threatened or endangered species, other domestic and wild animals suspected of being rabid should be euthanized and their tissues examined for the presence of rabies antigen by appropriate laboratory techniques.

c Bites especially on the head, neck, face, hands and genitals are category III exposures because of the rich innervation of these areas.

Post-exposure prophylaxis of previously non-immunised individuals

Vaccine should be administered on D0, D3, D7, D14 and D28 (5 injections of 0.5 mL).

For category III exposure (see Table 1), rabies immunoglobulin should be given in association with vaccine. In this case, the vaccine should be administered contralaterally, if possible.

Vaccination should not be discontinued unless the animal is declared not rabid according to a veterinarian assessment (supervision of animal and/or laboratory analysis).

Post-exposure prophylaxis of previously immunised individuals

Previously immunised individuals should receive one dose of vaccine intramuscularly on both days 0 and 3. Rabies immunoglobulin is not indicated in such cases.

According to WHO recommendation, previously immunised individuals are patients who can document previous complete PrEP (pre-exposure prophylaxis) or PEP (postexposure prophylaxis) and people who discontinued a PEP series after at least two doses of a cell culture rabies vaccine.

Special population- immunocompromised individuals

- Pre-exposure prophylaxis

The conventional 3-dose regimen should be used (see subsection "*Pre-exposure prophylaxis*") and serology testing of neutralising antibodies should be performed 2 to 4 weeks after the last dose to assess the possible need for an additional dose of the vaccine.

- Post-exposure prophylaxis

Only a full vaccination schedule should be administered. Rabies immunoglobulin should be given in association with the vaccine for both categories II & III

exposures (see Table 1).

Paediatric population

Paediatric individuals should receive the same dose as adults (0.5 mL).

Method of Administration

The vaccine is for intramuscular administration only. The vaccine should be administered into the deltoid muscle for adults and children or the anterolateral area of the thigh muscle in infants and toddlers.

For instructions on the reconstitution of the vaccine before administration, see section 6.6.

4.3 Contraindications

Do not use SPEEDA™ for pre-exposure immunization:

If you are allergic to Inactivated Rabies Virus*(L. Pasteur PV-2061 strain) or any of the other ingredients of this medicine (listed in section 6).

If you are suffering from acute disease or chronic disease at acute episode, you may postpone pre-exposure immunization as appropriate.

If serious adverse events occur after vaccination, the vaccine should not be administered until the cause is identified.

Do not use SPEEDA™ for post-exposure immunization:

If you are with a definite history of hypersensitivity to any of the ingredients of this vaccine, you should receive an alternative rabies vaccine without this ingredient to continue the original immunization procedure.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

As with any vaccine, vaccination with SPEEDA™ may not protect 100% of vaccinated individuals.

In subjects with a history of allergy there may be an increased risk of side-effects and this possibility should be taken into account.

As with all vaccines, appropriate facilities and medication such as epinephrine (adrenaline) should be readily available for immediate use in case of anaphylaxis or hypersensitivity following injection. The vaccine may contain traces of neomycin and betapropiolactone which are used during the manufacturing process. Caution must be exercised when the vaccine is administered to subjects with hypersensitivity to betapropiolactone, neomycin, and other antibiotics of the same class.

If Rabies Immunoglobulin is indicated in addition to SPEEDA™, then it must be administered at a different anatomical site to the vaccination site.

SPEEDA™ should not be administered to patients with bleeding disorders such as haemophilia or thrombocytopenia, or to persons on anticoagulant therapy unless the potential benefit clearly outweighs the risk of administration. If the decision is taken to administer SPEEDA™ in such persons, it should be given with caution with steps taken to avoid the risk of haematoma formation following injection.

Paediatric population

The potential risk of apnoea and the need for respiratory monitoring for 48-72 h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity.

4.5 Interaction with other medicinal products and other forms of interaction

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Immunosuppressive agents or other treatments can interfere with the production of

antibodies and lead to weaken or the failure of the vaccination. The response of neutralizing antibody should be monitored timely after vaccination.

4.6 Fertility, pregnancy and lactation

Pregnancy

Data in literature on limited number of exposed pregnancies do not allow a conclusion on the potential risk of SPEEDA™ for pregnancy or for the health of the foetus/newborn child. Due to the severity of disease, pregnancy is not considered a contraindication to post exposure prophylaxis. If there is substantial risk of exposure to rabies, pre-exposure prophylaxis may also be indicated during pregnancy.

Breastfeeding

Due to the severity of the disease, breast feeding is not considered a contraindication and treatment must not be discontinued. It is not known whether this vaccine is excreted in human breast milk, thus no recommendation on continuation/discontinuation of breastfeeding can be made.

Fertility

SPEEDA™ has not been evaluated for impairment of male or female fertility.

4.7 Effects on ability to drive and use machines

No studies have been carried out on the effect of SPEEDA™ on the ability to drive and use machines.

4.8 Undesirable effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Clinical studies experience

Very common (may affect more than 1 in 10 people): pain, fever, headache,

asthenia;

Common (may affect up to 1 in 10 people): tenderness, swelling, rash, vomiting, diarrhea;

Uncommon (may affect up to 1 in 100 people): induration, erythema;

Post-marketing experience

Cold intolerance, chest tightness, shortness of breath, palpitations, hypersensitivity reaction and dizziness.

Experience on clinical studies and post-marketing surveillance of similar products

Circulatory system disorder; lymphadenopathy (lymph node enlargement); urticarial, hyperhidrosis; myalgia, arthralgia, arthritis; anaphylactic reaction (include anaphylactic shock); encephalitis, threatened syncope, vertigo, acute disseminated encephalomyelitis, angioedema.

In case of adverse reactions, especially those not mentioned above, please contact your doctor or pharmacist.

4.9 Overdose

Not applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Rabies vaccines, ATC Code: J07BG01

Mechanism of action

SPEEDA™ (Pharmacotherapeutic group) can induce immunity against rabies virus in recipients following immunization, it is used to protect against rabies

Injection of SPEEDA™ leads to a specific immune response. Neutralization of the rabies virus by rabies antibodies plays a major role in the protection.

Pre-exposure prophylaxis

Three doses (0.5 mL/dose) should be administered intramuscularly on Day 0, Day 7 and Day 21 or Day 28.

Post-exposure prophylaxis

Essen regimen (1-1-1-1-1):

The five-dose (0.5 mL/dose) regimen is administered intramuscularly on Day 0, Day 3, Day 7, Day 14 and Day 28.

In clinical studies, SPEEDA™ elicited neutralizing antibodies (≥ 0.5 IU/mL) in 100% of patients within 14 days and 45 days, when administered according to the WHO-recommended schedule of Essen regimen.

Paediatric population

Immunogenicity of 2-dose pre-exposure rabies vaccine co-administered with quadrivalent influenza vaccine by IM route has been assessed in 100 children from 3 to 9 years of age in a published literature. All participants achieved protective RVNA titers (≥ 0.5 IU/mL) on Day 42 and 7-days post booster. The 2-dose PrEP regimen of rabies vaccine produces adequate immune response either 0, 7 or 0, 28 regimens.

A trial study of immunogenicity between rabies vaccine (Vero cell) and rabies vaccine (purified chick embryo cell) with Essen regimen by IM route has been assessed in 36 subjects (18 subjects of < 5 years and 18 subjects of 5~18 years). All participants achieved protective RVNA titers (≥ 0.5 IU/mL) at Day 365 post-immunization.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Preclinical studies were conducted to evaluate the toxicity, local tolerance and

active systemic anaphylaxis reactions on laboratory animals. The results showed no potential safety concerns regarding the clinical use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Human serum albumin, dextran 40, phosphate buffered saline (sodium chloride, sodium dihydrogen phosphate dihydrate and disodium hydrogen phosphate dodecahydrate)

Diluent: sterile water for injection

6.2 Incompatibilities

In the absence of compatibility studies, this vaccine should never be combined in the same syringe or injected into the same site with other medicinal products.

6.3 Shelf life

36 months

Do not use this medicine after the expiry date which is stated on the label and box.

6.4 Special precautions for storage

Store between +2 ˚C and +8 ˚C. Protect from light. Do not freeze.

6.5 Nature and contents of container

Powder (lyophilized vaccine):

Single dose in a vial (Neutral Borosilicate Glass) with a stopper (Halogenated Butyl) and a cap (Aluminum-plastic multi-cap).

Solvent (diluent, sterile water for injection):

Single dose in an ampoule (Neutral Borosilicate Glass).

Presentations

- Box of 1 dose contains:

Vaccine 1 vial (@ 1 dose), diluent 1 ampoule (@ 0.5 mL) and 1 disposable syringe

- Box of 5 doses contains:

  Vaccine 5 vials (@ 1 dose) and diluent 5 ampoules (@ 0.5 mL)

6.6 Special precautions for disposal

To reconstitute the vaccine, introduce the diluent 0.5 mL into the vial of powder and shake thoroughly until the powder is dissolved completely. The solution should be homogenous, clear and free of any particles. Withdraw the solution in a syringe.

7. MARKETING AUTHORISATION HOLDER

Name and address: Liaoning Cheng Da Biotechnology Co., Ltd., No.1, Xinfang Street, Human New District, Shenyang, China.

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E-mail: cdbio@cdbio.cn

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

Country: Republic of Armenia

Name and address: Meliora Pharm Ltd., Apartment 11, Building 37, Nalbandyan Street, Yerevan, 0001-Republic of Armenia

Tel: +37491 799195

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8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

N/A